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ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.*

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(54) Title: THE USE OF NON-DIGESTIBLE POLYMERIC FOAMS TO SEQUESTER INGESTED MATERIALS, THEREBY INHIBITING THEIR ABSORPTION BY THE BODY

(57) Abstract: This disclosure relates to compositions comprising an open-celled polymeric foam wherein the compositions are useful for sequestering lipophilic materials present in the gastrointestinal tract, thereby inhibiting the absorption of such lipophilic materials by the body. The disclosure further relates to compositions comprising the open-celled polymeric foam wherein the compositions are useful for ameliorating side effects associated with the use of lipase inhibitors. In a preferred embodiment, this disclosure relates to compositions comprising polymeric foam materials made from high internal phase emulsions, where such foams are useful for sequestering lipophilic materials. Further disclosed are compositions comprising open-celled polymeric foams wherein the compositions are useful for the purpose of sequestering aqueous and/or hydrophilic materials present in the gastrointestinal tract, thereby ameliorating diarrhea. Kits comprising the compositions and methods of using the compositions and kits are also described.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/06529

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K31/74 A61P1/00 A61P1/12 A61P3/04 A61P3/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K A61P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

BIOSIS, MEDLINE, EPO-Internal, FSTA, EMBASE, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 51408 A (PARK KINAM) 19 November 1998 (1998-11-19) abstract page 57, line 15-25 ---	1-3,7-10
X	DE 199 42 365 A (BEISEL GUENTHER) 15 March 2001 (2001-03-15) the whole document ---	1-3,7-10
E	EP 1 214 934 A (WILLMEN HANS RAINER ;RATJEN WERNER (DE)) 19 June 2002 (2002-06-19) abstract claims 1-7,30 ---	1-3,7,8
X	WO 01 17377 A (BEISEL GUENTHER) 15 March 2001 (2001-03-15) claims ---	1-3,7-10
-/--		

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

19 November 2002

Date of mailing of the international search report

28/11/2002

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/06529

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 901 792 A (SUWELACK SKIN & HEALTH CARE AG) 17 March 1999 (1999-03-17) abstract ----	1-3,7-10
X	MARKOVA E A: "TREATMENT OF ALIMENTARY OBESITY WITH OXYGEN FOAM" VRACHEBNOE DELO, vol. 6, 1971, pages 106-108, XP001120225 ISSN: 0049-6804 abstract ----	1,2,7,8
X	US 6 048 908 A (KITAGAWA NAOTAKA) 11 April 2000 (2000-04-11) column 15, line 3-7 ----	1-4
A	US 5 650 222 A (DYER JOHN COLLINS ET AL) 22 July 1997 (1997-07-22) cited in the application the whole document -----	1-10

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 02/06529

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 7-9 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos.: 1-10 (in part)
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1-10 (in part)

Present claim 1 relate to a composition defined by reference to a desirable characteristic or property, namely "a non-digestible, non-absorbable, open-celled polymeric foam"

The claims cover all compositions having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and disclosure within the meaning of Article 5 PCT for only a very limited number of such compositions. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the composition by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. The above objection is also valid for dependent claims 2, 3, 5, 6 and claims 7-10, inasfar as they rely on the above definition of the composition.

Moreover, "sequestering one or more lipophilic materials present in the gastrointestinal tract of the animal" relates to the mode of action of the agent, and is not a clear description of a disease (Art. 6 PCT).

Consequently, a full search could only be carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the the use of HIPE foams (claim 4) in the treatment of the disorders listed in claim 8.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 02/06529

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9851408	A	19-11-1998	US 6271278 B1	07-08-2001
			AU 736940 B2	09-08-2001
			AU 6932698 A	08-12-1998
			BR 9809815 A	27-06-2000
			CN 1264321 T	23-08-2000
			EP 0988108 A1	29-03-2000
			WO 9851408 A1	19-11-1998
			JP 2002501563 T	15-01-2002
			US 2001038831 A1	08-11-2001
DE 19942365	A	15-03-2001	DE 19942365 A1	15-03-2001
			AU 7001300 A	10-04-2001
			WO 0117510 A1	15-03-2001
			EP 1210070 A1	05-06-2002
EP 1214934	A	19-06-2002	DE 10062624 A1	20-06-2002
			EP 1214934 A2	19-06-2002
WO 0117377	A	15-03-2001	DE 19942417 A1	08-03-2001
			DE 29915656 U1	20-04-2000
			AU 7650100 A	10-04-2001
			WO 0117377 A1	15-03-2001
			EP 1209988 A1	05-06-2002
EP 0901792	A	17-03-1999	DE 19739031 A1	11-03-1999
			AU 709337 B2	26-08-1999
			AU 7864098 A	18-03-1999
			CA 2245754 A1	05-03-1999
			DE 29723220 U1	28-05-1998
			EP 0901792 A1	17-03-1999
			JP 3045388 B2	29-05-2000
			JP 11139993 A	25-05-1999
US 6048908	A	11-04-2000	AU 8154298 A	19-01-1999
			EP 0993337 A1	19-04-2000
			JP 2002507975 T	12-03-2002
			WO 9900187 A1	07-01-1999
			US 6218440 B1	17-04-2001
US 5650222	A	22-07-1997	US 6107538 A	22-08-2000
			US 6372953 B1	16-04-2002
			US 6426445 B1	30-07-2002
			US 5741581 A	21-04-1998
			US 5744506 A	28-04-1998
			AU 713565 B2	02-12-1999
			AU 4895796 A	31-07-1996
			BR 9606740 A	30-12-1997
			CA 2209928 A1	18-07-1996
			CN 1175959 A	11-03-1998
			CZ 9702127 A3	17-12-1997
			DE 69615338 D1	25-10-2001
			DE 69615338 T2	04-07-2002
			EG 20968 A	30-07-2000
			EP 0802929 A1	29-10-1997
			ES 2161348 T3	01-12-2001
			FI 972913 A	09-09-1997
			JP 3288710 B2	04-06-2002
			JP 11500763 T	19-01-1999

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/06529

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5650222	A	NO 973183 A	10-09-1997
		TR 9700617 T1	21-02-1998
		WO 9621680 A1	18-07-1996
		ZA 9600137 A	30-07-1996
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